DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Myfortic
Docket No. FDA-2004-E-0267
Previously: 2004E-0325

MAY 25 2011

The Honorable David Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This letter is in regard to the application for patent term extension for U.S. Patent No. 6,306,900 filed by Novartis AG under 35 U.S.C. section 156. Please refer to the letters dated June 7, 2004, and February 6, 2006, from your Office of Patent Legal Administration, as well as FDA's letter of October 19, 2004, regarding this issue. The human drug product claimed by the patent is Myfortic (mycophenolic acid), which was assigned new drug application (NDA) No. 50-791.

With regards to the question of whether the active ingredient in Myfortic is mycophenolic acid or mycophenolate sodium, FDA confirms that the active ingredient, as that term is defined under 35 U.S.C. section 156(f)(2) and recently interpreted by the Federal Circuit, is mycophenolate sodium.[1] Although Myfortic's established name is mycophenolic acid, for the purposes of your inquiry, its active ingredient is mycophenolate sodium. Mycophenolic acid exists as a sodium salt in Myfortic tablets.

FDA has previously approved for commercial marketing or use mycophenolate mofetil, an ester of mycophenolic acid, as CellCept, NDA 50-722 (approved May 3, 1995). However, FDA has not previously approved for commercial marketing or use mycophenolate sodium itself, nor a salt or ester of mycophenolate sodium. We therefore confirm that Myfortic represents the first permitted commercial marketing or use of the drug product, as required by 35 U.S.C. section 156(a)(5)(A).

We have also reviewed the dates contained in the application and have determined the regulatory review period for Myfortic. The total length of the regulatory review period for Myfortic is 1,947 days. Of this time, 1,643 days occurred during the testing phase and 304 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 31, 1998.

[1] *See Photocure ASA v. Kappos*, 603 F.3d 1372, 1376 (Fed. Cir. 2010).

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 31, 1998.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: April 30, 2003.

FDA has verified the applicant's claim that the new drug application (NDA) for Myfortic (NDA 50-791) was initially submitted on April 30, 2003.

3. The date the application was approved: February 27, 2004.

FDA has verified the applicant's claim that NDA 50-791 was approved on February 27, 2004.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Dr. Leslie Fischer
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